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\*Admitted only in Maryland  
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 •Practice Limited to Federal Agencies

Commissioner for Patents  
 Washington, D.C. 20231

May 2, 2003

**WRITER'S DIRECT NUMBER:**  
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**INTERNET ADDRESS:**  
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RECEIVED  
 Art Unit 1614 06 2003  
 TECH CENTER 1600/2900

Re: U.S. Utility Patent Application  
 Appl. No. 09/956,980; Filed: September 21, 2001  
 For: **Agents for Use in the Treatment of Alzheimer's Disease**  
 Inventors: *Bush et al.*  
 Our Ref: 0609.4550001/JAG/FRC

Sir:

Transmitted herewith for appropriate action are the following documents:

1. Fee Transmittal Form (PTO/SB/17);
2. First Supplemental Information Disclosure Statement;
3. Listing of the cited documents on Form PTO-1449 (3 sheets);
4. A copy of each of the thirteen (13) cited documents on Form PTO-1449;
5. Our PTO-2038 Credit Card Payment Form in the amount of **\$180.00** to cover the fee under 37 C.F.R. § 1.17(p); and
6. Return postcard.

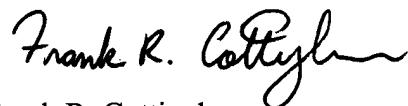
It is respectfully requested that the attached postcard be stamped with the date of filing of these documents, and that it be returned to our courier. In the event that extensions of time are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned.

Commissioner for Patents  
May 2, 2003  
Page 2

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Frank R. Cottingham  
Attorney for Applicants  
Registration No. 50,437

FRC/pcd  
Enclosures

::ODMA\MHODMA\SKGF\_DC1;129123;1

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

**FEE TRANSMITTAL**

for FY 2003

MAY 02 2003

Patent fees are subject to annual revision.

 Applicant claims small entity status. See 37 CFR 1.12.**TOTAL AMOUNT OF PAYMENT (\$)** **180.00**

Complete if known

**RECEIVED**

Application Number	09/956,980
Filing Date	September 21, 2001
First Named Inventor	Bush et al.
Examiner Name	Weddington, K.
Group Art Unit	1614
Attorney Docket No.	0609.4550001/JAG/FRC

**METHOD OF PAYMENT (check all that apply)**

- Check  Credit card  Money Order  Other\*\*  None  
 \*\* Charge any deficiencies or credit any overpayments in the fees or fee calculations of Parts 1, 2 and 3 below to Deposit Account No. 19-0036.

 Deposit Account  
Deposit Account Number 19-0036

Deposit Account Name: Sterne, Kessler, Goldstein &amp; Fox P.L.L.C.

**The Commissioner is authorized to: (check all that apply)**

- Charge fee(s) indicated below  Credit any over payments  
 Charge any additional fee(s) during the pendency of this application  
 Charge fee(s) indicated below, except for the filing fee to the above-identified deposit account.

**FEE CALCULATION (continued)****3. ADDITIONAL FEES****Large Entity** **Small Entity**

Fee Code	Fee (\$)	Fee Code	Fee (\$)	Fee Description	Fee Paid
1051	130	2051	65	Surcharge - late filing fee or oath	
1502	50	2052	25	Surcharge-late provisional filing fee or cover sheet	
1053	130	1053	130	Non-English specification	
1812	2,520	1812	2,520	For filing a request for ex parte reexamination	
1804	920*	1804	920*	Requesting publication of SIR prior to Examiner action	
1805	1,840*	1805	1,840*	Requesting publication of SIR after Examiner action	
1251	110	2251	55	Extension for reply within first month	
1252	410	2252	205	Extension for reply within second month	
1253	930	2253	465	Extension for reply within third month	
1254	1,450	2254	725	Extension for reply within fourth month	
1255	1,970	2255	985	Extension for reply within fifth month	
1401	320	2401	160	Notice of Appeal	
1402	320	2402	160	Filing a brief in support of an appeal	
1403	280	2403	140	Request for oral hearing	
1451	1,510	1451	1,510	Petition to institute a public use proceeding	
1452	110	2452	55	Petition to revive - unavoidable	
1453	1,300	2453	650	Petition to revive - unintentional	
1501	1,300	2501	650	Utility issue fee (or reissue)	
1502	470	2502	235	Design issue fee	
1503	630	2503	315	Plant issue fee	
1460	130	1460	130	Petitions to the Commissioner	
1807	50	1807	50	Processing fee under 37 CFR 1.17(q)	
1806	180	1806	180	Submission of Information Disclosure Stmt	180
8021	40	8021	40	Recording each patent assignment per property (times number of properties)	
1809	750	2809	375	Filing a submission after final rejection (37 CFR 1.129(a))	
1810	750	2810	375	For each additional invention to be examined (37 CFR 1.129(b))	
1801	750	2801	375	Request for Continued Examination (RCE)	
1802	900	1802	900	Request for expedited examination of a design application	

Other fee (specify) \_\_\_\_\_

\* Reduced by Basic Filing Fee Paid **SUBTOTAL (3) (\$)** **180.00****SUBMITTED BY**

Complete (if applicable)

Name (Print/Type)	Frank R. Cottingham	Registration No. (Attorney/Agent)	50,437	Telephone	202-371-2600
Signature				Date	MAY 2, 2003

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

This collection of information is required by 37 CFR 1.17 and 1.27. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, Washington, DC 20231.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2. SKGF\_DC1:129191



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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Bush *et al.*

Appl. No. 09/956,980

Filed: September 21, 2001

For: **Agents for Use in the Treatment  
of Alzheimer's Disease**

Confirmation No. 6687

Art Unit: 1614

Examiner: Weddington, K.

Atty. Docket: 0609.4550001/JAG/FRC

#131/2

**First Supplemental Information Disclosure Statement**

Commissioner for Patents  
Washington, D.C. 20231

Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98. The numbering on this First Supplemental Information Disclosure Statement is a continuation of the numbering in Applicants' Information Disclosure Statement filed on March 5, 2002, in connection with the above-captioned application. A copy of each document is also provided.

In accordance with 37 C.F.R. § 1.98(a)(3), Applicants' undersigned representative submits the following, concise explanation of the relevance of the non-English language document AM4 cited on Form PTO 1449:

Document AM4, DE 40 04 978 A1 is in the German language and appears to relate to the use of a synthetic complexing agent to eliminate aluminum ions as a therapy for Alzheimer's disease. An English language abstract of document AM4 is attached as document AT67.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached PTO-1449 based on information presently available to the undersigned. However, the listed publication dates

should not be construed as an admission that the information was actually published on the date indicated.

This Information Disclosure Statement is being filed more than three months after the U.S. filing date AND after the mailing date of the first Office Action on the merits, but before the mailing date of a Final Rejection, or Notice of Allowance, or an action that otherwise closes prosecution in the application. Attached is our PTO-2038 Credit Card Payment Form in the amount of \$ 180.00 in payment of the fee under 37 C.F.R. § 1.17(p).

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered. This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist.

Consideration of the cited documents and making the same of record in the prosecution of the above-identified application is respectfully requested. The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

  
Frank R. Cottingham  
Attorney for Applicants  
Registration No. 50,437

Date: MAY 02, 2003

1100 New York Avenue, N.W.  
Washington, D.C. 20005-3934  
(202) 371-2600



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FORM PTO-1449  FIRST SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT	ATTY. DOCKET NO. 0609.4550001/JAG/FRC	APPLICATION NO. 09/956,980
	APPLICANT Bush et al.	
	FILING DATE September 21, 2001	GROUP 1614

**U. S. PATENT DOCUMENTS**

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
AA						
AB						
AC						
AD						
AE						
AF2	4,419,365	12/06/1983	McLachlan			12/21/1983
AG2	5,310,936	05/10/1994	Regtop et al.			01/15/1992
AH						
AI						
AJ						
AK						

**FOREIGN PATENT DOCUMENTS**

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
AL						Yes No
AM4	DE 40 04 978 A1	08/22/1991	Germany			X Yes No
AN4	WO 94/27594 A2	12/08/1994	WIPO			Yes No
AO4	WO 96/39144 A1	12/12/1996	WIPO			Yes No
AP4	WO 97/01559 A1	01/16/1997	WIPO			Yes No

**OTHER (Including Author, Title, Date, Pertinent Pages, etc.)**

AR			
AS			
AT	65	BIOMOL Product Data for TPEN, Catalog No. AP-300, BIOMOL Research Laboratories, Inc. Plymouth Meeting, PA	

EXAMINER \_\_\_\_\_ DATE CONSIDERED \_\_\_\_\_

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.



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Page 6 of 26

		ATTY. DOCKET NO. 0609.4550001/JAG/FRC	APPLICATION NO. 09/956,980
		APPLICANT Bush et al.	
<u>FIRST SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT</u>		FILING DATE September 21, 2001	GROUP 1614

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	AF						
	AG						
	AH						
	AI						
	AJ						
	AK						

## FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	<u>66</u>	Cardelli, M.B., et al., "Chelation Therapy. Unproved Modality in the Treatment of Alzheimer-Type Dementia," <i>J. Am. Geriatr. Soc.</i> 33:548-551, Blackwell Science (1985)
AS	<u>66</u>	Ishii, T., and Bannai, S., "The Synergistic Action of the Copper Chelator Bathocuproine Sulphonate and Cysteine in Enhancing Growth of L1210 Cells In Vitro," <i>J. Cell. Physiol.</i> 125:151-155, Alan R. Liss, Inc. (1985)
AT	<u>66</u>	Kruck, T.P.A., et al., "Suppression of deferoxamine mesylate treatment-induced side effects by coadministration of isoniazid in a patient with Alzheimer's disease subject to aluminum removal by ionspecific chelation," <i>Clin. Pharmacol. Ther.</i> 48:439-446, Mosby-Year Book (1990)

EXAMINER

DATE CONSIDERED

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Page 3 of 3

FORM PTO-1449  <u>FIRST SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT</u>		ATTY. DOCKET NO. 0609.4550001/JAG/FRC	APPLICATION NO. 09/956,980
		APPLICANT Bush et al.	
		FILING DATE September 21, 2001	GROUP 1614

**U.S. PATENT DOCUMENTS**

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	AA						
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	AH						
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	AJ						
	AK						

**FOREIGN PATENT DOCUMENTS**

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

**OTHER (Including Author, Title, Date, Pertinent Pages, etc.)**

AR	<u>67</u>	"9579. Trientine," in <i>The Merck Index: An encyclopedia of chemicals, drugs, and biologicals</i> , 11 <sup>th</sup> edition, Budavari, S., et al., eds., Merck & Co., Inc., Rahway, N.J., p. 1521 (1989)
AS	<u>67</u>	Van Reyk, D.M., and Dean, R.T., "The Iron-selective Chelator Desferal Can Reduce Chelated Copper," <i>Free Radic. Res.</i> 24:55-60, Harwood Academic Publishers GmbH (January 1996)
AT	<u>67</u>	Dialog File 351, Accession No. 8749401, Derwent WPI English language abstract for DE 40 04 978 A1 (Document AM4)

EXAMINER	DATE CONSIDERED
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EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.